

Supporting Statement for OMB Review
0910-0533

Experimental Study of Trans Fat Claims on Foods

Submitted by:

Office of Scientific Analysis and Support
Division of Market Studies
Food and Drug Administration
Department of Health and Human Services

March 17, 2003

Experimental Study of Trans Fat Claims on Foods

Supporting Statement for Information Collection Request

A. JUSTIFICATION

A.1 Necessity for the Information Collection

The Food and Drug Administration (FDA) regulates the labeling of food products under the Food, Drug and Cosmetic Act of 1938 (FDCA) and the Nutrition Labeling and Education Act of 1990 (NLEA).

As part of the overall FDCA mandate to encourage informed consumer choice, the NLEA mandates FDA to take account of the public health goal of encouraging healthy dietary practices in the population by encouraging label statements on food products that help consumers place products in the context of their total diet. Nutrient content claims are regulated under this authority. They are considered signals to consumers that products that bear such claims can appropriately play dietary roles that may lead to desirable health benefits. As such, they are subject to certain restrictions to ensure that consumers are given correct signals that are truthful and not misleading.

In November 1999, FDA proposed (64 FR 62746) to amend regulations on nutrition labeling to require that the amount of trans fatty acids (trans fat) present in a food be included on the Nutrition Facts Panel (NFP). The

purpose of the proposal was to better enable consumers to understand the contribution of the product to a total diet as mandated by NLEA. Mandatory disclosure of trans fat amounts was also as a necessary requirement to define nutrient content claims for trans fat. In the proposal, FDA agreed with the argument made by a petitioner that consumers need to know the levels of trans fat in a food product to be able to judge the nutritional significance of that product in the context of the total diet. Dietary trans fatty acids, like saturated fats, have adverse effects on blood cholesterol levels and the public health recommendation is to keep intake as low as possible.

The agency initially proposed that trans fat levels be disclosed on the NFP as part of the saturated fat declaration (combining the gram amount of saturated fat and trans fat and recalculating the percent DV to include trans fat). A footnote was required to indicate the amount of trans fat included in the combined amount.

Comments to the proposal argued against combining trans and saturated fat amounts into a single amount on grounds that there was no scientific or public health basis for applying the saturated fat DV to the combined amount. In November 2002, the agency reopened the comment period and proposed that the declaration of trans fat on the NFP be on a separate line immediately under that for saturated fat without an accompanying percent

DV declaration, but with an accompanying footnote stating, “intake of trans fat should be as low as possible”. The purpose of the accompanying footnote was to ensure that the trans fat information “be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet.”

Several comments challenged the agency’s assumptions about how the accompanying footnote would be interpreted by consumers. Three separate research studies were submitted (CSPI, Conagra, IFIC) that showed limitations in the public’s ability to use and understand the quantitative trans fat information in the presence of the proposed footnote. These studies provide some empirical evidence to support arguments made in a number of other comments that the proposed footnote might distort the appropriate understanding of the dietary significance of trans fat relative to other fatty acids, thereby causing the public to make poorer, rather than better, product choices. Since this is the opposite of the intended effect of the proposed footnote, the agency has determined that a systematic study is required to assess what kinds of footnotes or other decision aids are best able to help the public use the quantitative trans fat information in the NFP “to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet.”

The consumer behavior problem demonstrated by the CSPI, Conagra and IFIC studies is that when consumers look at the NFPs of two products with different fatty acid profiles in the presence of the proposed footnote, they are more likely to choose the product with less trans fat even when the other product has a better (i.e., healthier) fatty acid profile. The CSPI study compared the effect of the proposed footnote with a no footnote condition and a modified footnote that said “Combined total intake of saturated and trans fats should be as low as possible.” The quality of product choices (percent respondents who choose the healthier product/percent respondents who choose the less healthy product) declined in the presence of the proposed footnote, but improved with the modified footnote. In the Conagra study, the proposed footnote condition was the only one tested. Respondents who made the “wrong” product choice, i.e., choose the product with more total fat or more combined saturated and trans fat, tended to justify their choice in terms of the selected product having less trans fat. It is also noteworthy that two thirds of respondents indicated they did not know how to interpret (and therefore how to apply) the proposed footnote information. In the IFIC study, respondents were asked to compare two products repeatedly as more information was revealed about the two products (including trans fat information and footnotes). The quality of respondent choices deteriorated as more information was given that focused their attention on trans fat levels.

Each of these studies have serious limitation that render their findings suggestive but not definitive from the perspective of evaluating policy options. The CSPI and Conagra studies employ a much too restricted range of products to generalize confidently to the full range of products in the marketplace. The IFIC study uses within-subject manipulations of information conditions subject to experimental demand biases that may compromise the validity of its findings. Moreover, none of the studies evaluates a broad range of possible policy options the might be considered applicable to the problem of how best to inform consumers about the dietary significance of trans fat information on the food label.

One implication of the unexpected effects of footnote statements about recommended dietary levels of trans is that they suggest a similar phenomenon may occur when consumers see a nutrient content claim about the level of trans in a food product or a related claim. A likely interpretation of a nutrient content claim of ‘0 trans’ or ‘reduced trans’ or some equivalent language on a product label is that low levels of trans must be a highly positive product characteristic. Such a claim draws attention to and emphasizes the desirability of low trans levels just as the proposed footnote does. It may be that such claims lead consumers to overweight the importance of a product having low levels of trans and to ignore or underweight the importance of the overall fatty acid profile of

the product. Such a phenomenon, if it exists, may be relevant to labeling policy since nutrition content claims are one of the primary tools that food manufacturers can employ to promote food products. If such claims are misleading in the way that seemingly innocuous dietary guidance footnotes seem to be misleading there may be reason to restrict nutrient content claims in some circumstances.

The information objectives for the study are as follows:

1. Evaluate the impact of ‘low trans’ or ‘trans free’ nutrient content claims on consumer understanding of product characteristics across a representative range of product types likely to make such claims..
2. Evaluate the role that consumer ability to interpret and use fatty acid profile information about products plays in mediating the impact of ‘low trans’ or ‘trans free’ nutrient content claims.
3. Assess effectiveness of labeling options intended to help consumers interpret and use trans-related nutrient content claims. Such labeling options may include short statements of nutrition guidance on the principal display panel (PDP), front panel disclosure of saturated fat

information, labeling statements “see back panel for more information,” and other possible labeling options.

A2. How, By Whom and the Purpose for Collecting This Information

In order to achieve its intended objectives, the study employs an experimental design where effects of various proposed labeling options such as short statements of nutrition guidance on the principal display panel (PDP), front panel disclosure of saturated fat information, labeling statements such as “see back panel for more information,” and other possible labeling options are estimated by exposing random samples of subjects to controlled experimental conditions. Stimulus differences between conditions consist entirely of the experimentally manipulated label treatments that embody different possible versions of labeling statements intended to help consumers use and interpret trans fat claims on food products. Because individual differences are randomly distributed across conditions, it is possible to use standard statistical techniques such as analysis of variance and multivariate regression analysis to test observed treatment effects between conditions.

The study uses an internet panel methodology which has proved substantially equivalent to mall intercept methodologies in that it allows visual presentation of study materials, experimental manipulation of study materials, and the random assignment of subjects to condition. The study will use as its sample frame a large nationally representative consumer panel with 600,000 households, .

Participants will be adults, age 18 and older, who are recruited for a study about foods and food labels. Each participant will be randomly assigned to one of the 124 experimental conditions.

Based on the information objectives, the effects of possible policy options need to be measured in terms of judgment accuracy: (1) ability of respondents to make correct decisions when selecting products, (2) to make correct attributions about the nutritional values of a product, (3) to correctly judge how a product contributes to the total diet.

One way to impose a metric for measures of judgment accuracy is to vary the objective characteristics of stimuli. The relevant dimension for this study is the quality of the fatty acid profile of the product that bears the nutrient content claim. We propose to systematically vary the quality of the fatty acid profile for each type of product presented in the study such that there will be three conditions:

1) Good Profile: All components of the product fatty acid profile, saturated fat, trans fat, cholesterol and total fat will be good for the product type.

2) Medium Profile: The trans fat level and the cholesterol level will be good for the product type, but total fat and saturated fat will be moderate.

3) Poor Profile: The trans fat level will be low for the product type, but total fat, cholesterol and saturated fats levels will be moderate to high.

In this way, we can observe the effect of the actual fatty acid profile on subjects judgments about the product as well as the effect of possible nutrient content claims and accompanying information statements.

Product Types

It is necessary to demonstrate the generalizability of observed effects across a representative range of product types to ensure that some unique aspect of a certain product type is not responsible for the observed effects.

We propose to include three product types in the study that represent typical kinds of product that may bear trans fat relevant nutrient content claims:

- 1) Margarine**
- 2) Crackers**
- 3) Pound Cake.**

The relevant nutrient profile information for products considered good, medium, or poor by accompanying trans fat nutrient claim is described below.

Margarine (amount per 1 tablespoon serving) 32 kcal

Trans fat free

Good: 0.5 g *trans* fat, 0.5 g saturated fat, 0 mg cholesterol,

Medium: 0.5 g *trans* fat, 1.0 g saturated fat, 0 mg cholesterol

Poor: 0.5 g *trans* fat, 2.5 g saturated fat, 0 mg cholesterol

Reduced *trans* fat (25%)

(Reference food: 11 g total fat, 2.0 g *trans* fat, 2.0 g saturated fat, 0 mg cholesterol)

Good: 1.5 g *trans* fat, 0.5 g saturated fat, 0 mg cholesterol,

Medium: 1.5 g *trans* fat, 1.0 g saturated fat, 0 mg cholesterol

Poor: 1.5 g *trans* fat, 2.0 g saturated fat, 0 mg cholesterol

Cracker (amount per 10 cracker serving) 150 kcal

Trans fat free

Good: 0.5 g *trans* fat, 0.5 g saturated fat, 0 mg cholesterol,

Medium: 0.5 g *trans* fat, 1.5 g saturated fat, 0 mg cholesterol

Poor: 0.5 g *trans* fat, 3.0 g saturated fat, 0 mg cholesterol

Reduced *trans* fat (40%)

(Reference food: 6 g total fat, 2.5 g *trans* fat, 2.0 g saturated fat, 0 mg cholesterol)

Good: 1.5 g *trans* fat, 0.5 g saturated fat, 0 mg cholesterol,

Medium: 1.5 g *trans* fat, 1.5 g saturated fat, 0 mg cholesterol

Poor: 1.5 g *trans* fat, 3.0 g saturated fat, 0 mg cholesterol

Pound cake (amount per 1 slice serving) 120 kcal

Trans fat free

Good: 0.5 g *trans* fat, < 0.5 g saturated fat, 64 mg cholesterol,

Medium: 0.5 g *trans* fat, 2.0 g saturated fat, 64 mg cholesterol

Poor: 0.5 g *trans* fat, 3.5 g saturated fat, 300 mg cholesterol

Reduced *trans* fat (33%)

(Reference food: 16 g total fat, 4.5 g *trans* fat, 3.5 g saturated fat, 64 mg cholesterol)

Good: 3.0 g *trans* fat, 0.5 g saturated fat, 64 mg cholesterol,

Medium: 3.0 g *trans* fat, 2.0 g saturated fat, 64 mg cholesterol

Poor: 3.0 g *trans* fat, 3.5 g saturated fat, 300 mg cholesterol

Trans Fat Nutrient Content Claims and Interpretive Aids.

We propose to test two forms of trans fat relevant nutrient content claims:

- 1) Trans fat free (< 0.5 g trans fat per serving)**
- 2) Reduced trans fat (> 25% trans fat compared to reference amount)**

In addition we propose to include a label with no trans content claims, and trans content claims with accompanying labeling information that might help improve judgment accuracy:

- 3) No Content Claim**
- 4) Trans Fat Claim w. front panel disclosure of saturated fat and cholesterol content.**
- 5) Trans Fat Claim w. “see back panel for important information about saturated fat and cholesterol content”**

6) Trans Fat Claim w. selected nutrition guidance message, e.g., “keep your intake of **saturated fat,trans fat and cholesterol low** ”

7) Trans Fat Claim w. front panel disclosure of saturated fat and cholesterol content w. selected nutrition guidance message.

Full Information/No Information Treatment

Given the current low level of trans fat knowledge in the population, and the avowed aim of the trans fat labeling policy to increase such knowledge, we propose to systematically manipulate trans fat knowledge of respondents. Respondents in the full information condition will be briefed about relevant facts concerning trans fat prior to seeing any product labels. Respondents in the no information will not be given any information about trans fat. The manipulation of prior knowledge will allow evaluation of the effectiveness of policy options under conditions approximating the current distribution of knowledge in the population as well as conditions representing familiarity with the nutritional consequences of the trans fat.

The current draft of a full information statement for trans fat is as follows, but the draft may be modified based on wording suggestions from reviewers and from pretesting .

Fat is a major source of energy for the body and aids in the absorption of vitamins A, D, E, and K, and carotenoids. The main types of fatty acids found in unprocessed foods are saturated, monounsaturated and polyunsaturated fats. *Trans* fat (also known as *trans* fatty acids) is a kind of fat formed when liquid oils are hydrogenated or partially hydrogenated during processing. *Trans* fat in food products extends shelf life and has desirable taste characteristics. *Trans* fat behaves in the body like saturated fat by raising low-density lipoprotein (LDL or "bad") cholesterol that increases your risk of coronary heart disease (CHD). *Trans* fat can be found in foods made with partially hydrogenated vegetable oils

such as vegetable shortenings, some margarines, crackers, candies, cookies, snack foods, fried foods, baked goods, and other processed foods. On average, Americans consume approximately 4 to 5 times as much saturated fat as *trans* fat in their diet. When choosing foods, it is important to consider the total amount of saturated and trans fat in the food as well as cholesterol. Most health professionals recommend that you should reduce your consumption of saturated fat, trans fat and cholesterol to reduce the risk of heart disease.

Experimental Design

The basic experimental design is

Information Treatment (Full/None) X Product Type (Margarine, Crackers, Pound Cake) X Fatty Acid Profile (Good, Moderate, Poor) X Label Treatment Condition (7) resulting in a fully crossed design with 126 conditions.

Since the key experimental hypotheses concern the effects of the labeling conditions on judgment accuracy, we expect to collapse across product type conditions when testing the experimental hypotheses. We estimate that 20 subjects per cell, 2,560 subjects in all, will provide adequate power to identify small to medium size effects (i.e., $r = .15-.30$) for all main effects and first order interactions with power = $(1-\beta)$ well in excess of .80 at the .05 significance level. Power for second and third order interactions will necessarily be smaller, but even for third order interactions, statistical power will be $\approx .80$ at the .10 significance level.

Study Protocol.

Procedures. Participants will view two-dimensional color mock-ups of food labels. For each product, the front panel will be presented first, followed by some questions about the front panel (see questionnaire). Then the participant will look at the back panel of the product label that contains a Nutrition Facts Panel (NFP) for the food product. Respondents then answer a series of product perception questions (see questionnaire) related to expected health benefits and perceived nutritional characteristics of the product.

During the product perception questions, both the front and back label will be available to the participant.

In the Full Information condition, respondents will read a one-page summary of the current state of scientific evidence for the health effects of trans fat in the diet. It will be written at a 6th-8th-grade reading level. Nutrition scientists at FDA will review the summaries for accuracy. The Full Information summary will be presented prior to viewing any labels

Measures. The key measures for the study are product perception questions about the labeled food product (expected health benefits, perceived nutrition ratings).

Product Perception Questions

1. How likely is it that eating this food as a regular part of one's diet would reduce the risk of [disease/health condition]? 7-point rating scale from 1 ("very likely" all) to 7 ("not at all likely")

Will be asked for three health conditions (heart disease, high blood cholesterol, and overweight).

2. Do you consider this product to be high, medium or low in...[list of nutrients- Total fat, calories, sodium, cholesterol, trans fat, saturated fat]?
3. Overall, how important would this food be as part of a healthy diet? On a scale from 1 to 7 where 1 means "very important" and 7 means "not at all important."

Background questions will include standard demographics, knowledge questions about fatty acids and cholesterol, current label use, and health status.

Analysis Plan

This study can be viewed as an evaluation of the impact of trans fat content claims on judgment accuracy. Judgment accuracy will be bounded by the performance of subjects in several comparison conditions who see no content claims, who have previously been "fully informed" about trans fat, and who see the same product with varying fatty acid profile quality. The impact of content claims and accompanying information statements will be assessed by estimating the discrepancy between respondent judgments made under these conditions compared to respondent judgments made under the respective comparison

conditions. It will be possible to estimate the experimental effects of content claims and accompanying claims compared to no claims, depending on whether respondents are fully informed or not, and depending on the actual quality of the product's fatty acid profile. Analysis of variance with specific contrasts and multivariate regression techniques will be used.

The Office of Nutritional Products, Labeling and Dietary Supplements (ONPLDS) is the primary user of this information. The information provided by the study will inform regulatory initiatives announced in the June 2003 ANPR. The results will be made available as part of the docket so that all interested parties can comment on and benefit from the findings.

A3. Use of Technology to Reduce the Burden on the Public

The study relies on a commercially available internet panel to be the sample frame from which samples of respondents can be randomly drawn to be assigned to condition. Data collection will take place over the internet.

A4. Identification and Use of Duplicate Information

The proposed study is based in part on several studies submitted as comments to the trans fat rule (CSPI, 2003; IFIC, 2003, Conagra, 2003). In addition, FDA is aware of a number of studies that have evaluated the impact of nutrient content claims on consumer perception of product characteristics (see References). The procedures and measures used in this study are wholly consistent with this previous research. However, none of the previous research has addressed the specific issue of trans fat

claims, and in this respect the present research will advance our understanding of the area.

A5. FDA's Efforts to Reduce Burden on Small Business

There is no impact on small business from this data collection.

A6. Impact of Not Collecting This Information or Collecting Information Less Frequently

This study is a one-time data collection. FDA is trying to finalize its trans fat regulations in anticipation of the 2006 effective date for mandatory disclosure of trans fat on the NFP. Possible requirements for trans fat nutrient content claims and the form and content of educational initiatives intended to help consumers better understand and use trans fat information will necessarily be informed by the findings of the proposed study.

A7. Special Circumstances That Occur When Collecting This Information

No special circumstances.

A8. Identification of Outside FDA sources

Consumer understanding of trans fat declarations and possible trans fat nutrient content claims has been the subject of extensive public comments since the November 1999 publication of the proposed rule. Comments were carefully considered in the formulation of the present research design. Important features of the proposed study are, in fact, based on preliminary research from industry, consumer groups and public health organizations.

The revised proposal was sent to three external peer reviewers at academic institutions with expertise in consumer research and labeling topics. The reviewers

provided comments on the study design and questionnaire. The proposed study incorporates the comments from the peer reviewers.

Peer Reviews:

1. Manoj Hastak, PhD
Associate Professor and Chair of Marketing Department
Kogod School of Business
American University, Washington, DC
2. Alan Mathios, PhD
Associate Professor and Department Chairperson
Department of Policy Analysis and Management
Cornell University, Ithaca, NY
3. Debra Ringold, PhD
Associate Dean and Professor of Marketing
Atkinson School
Willamette University, Salem, Oregon

A9. Payment or Gifts Offered to

The proposed study uses an existing consumer internet panel as its sample frame.

Participants complete interview instruments without specific reimbursement, but they receive small tokens of appreciation and are eligible for prizes as a consequence of their ongoing participation.

A10. Method of Ensuring Confidentiality

No identifying information about individual respondents is included in the data file or other information provided to the government by the contractor

A11. Use of Sensitive Questions

This study does not include any sensitive questions.

A12. Burden Hours and Cost Associated With This Information Collection.

The total sample is 2,560. Based on past experience, the interview length will average 15 minutes.

Estimated Annual Reporting Burden

Number of	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
2,560	1	2,560	.25	640

There are no capital costs or operating and maintenance costs associated with this collection of information.

A13. Annual Cost Estimate to

There are no costs associated with this data collection outside the burden reflected in A12.

A14. Annual Cost Estimate to FDA

FDA has contracted with Synovate/Market Facts for data collection services.

Peer reviewers were paid under personal services contracts.

Contractor estimated cost = \$199,969

Peer reviewers = \$ 5,700

Total = \$205,669

A15. Changes from Previous Approval

This is a new project.

A16. Publishing the Results of This Information Collection

A final report of the study procedures and results will be issued at the end of the data collection period, as specified in the contract. The results will be presented to FDA management and the report will be made available to the docket and on FDA's website, as part of any future proposed rulemaking on trans fat claims and footnotes. It is

anticipated that the findings will be presented in FDA reports and in publications in scientific journals.

A17. Reason for Not Displaying the OMB Approval Date

The OMB Approval Date will be displayed on the questionnaire.

A18. Explanations to Section 19, “Certification for Paperwork Reduction Act Submissions”

No exceptions are requested.

Part B COLLECTION OF INFORMATION USING STATISTICAL METHODS

B1. Universe and Sampling

The study uses an internet panel methodology which has proved substantially equivalent to mall intercept methodologies in that it allows visual presentation of study materials, experimental manipulation of study materials, and the random assignment of subjects to condition. The study will be implemented in a large nationally representative consumer panel with 600,000 households. The consumer mail panel includes consumers who span the full range of education, age, race and income characteristics in the population. By implementing the study in such a sample frame the generalizability of the findings to a large fraction of the general population is ensured.

Participants will be adults, age 18 and older, who agree to participate in a study about foods and food labels. Each participant will be randomly assigned to one of the 126 experimental conditions.

B2. Procedures for Collecting the Information

Participants will be asked to thoroughly review the package labeling of products presented to them and then answer questions about the product's perceived health benefits, choice preferences, risk/benefit tradeoffs, and other questions (see attached questionnaire).

Participants will view two-dimensional color mock-ups of food labels. For each product, the front panel will be presented first, followed by some questions about the front panel (see questionnaire). Then the participant will look at the back panel of the product label that contains a Nutrition Facts Panel (NFP) for the food product. Respondents then answer a series of product perception questions (see questionnaire) related to expected health benefits and perceived nutritional characteristics of the product.

During the product perception questions, both the front and back label will be available to the participant.

In the Full Information condition, respondents will read a one-page summary of the current state of scientific evidence for the health effects of trans fat in the diet. It will be written at a 6th-8th-grade reading level. Nutrition scientists at FDA will review the summaries for accuracy. The Full Information summary will be presented prior to viewing any labels

B3. Methods to Increase or Maximize the Response Rates

Participants are sent multiple reminders asking them to complete the interview instrument. Because participants are practiced at accessing and completing such instruments, no additional measures are necessary.

B4. Tests, Procedures, or Methods Used

The contractor will conduct nine pretests to test procedures. Changes to procedures or the questionnaire will be submitted to OMB prior to data collection.

B5. Identification of Consultation

The contact individuals are Alan S. Levy, Ph.D., Division of Market Studies, Consumer Studies Team, HFS-727, telephone (301) 436-1762 (Project Officer), and Brenda Derby, Ph.D., Division of Market Studies, Consumer Studies Team, HFS-727, telephone (301) 436-1832 (Statistician), and David B. Lambert, Ph.D., Senior Vice President, TNS Intersearch, (215) 442-9638.

References

Andrews, J.C., Burton, S. & Netemeyer, R.G. Are some comparative nutrition claims misleading? The role of nutrition knowledge, ad claim type, and disclosure conditions. *Journal of Advertising*, in press.

Andrews, J. C., Netemeyer, R.G. & Burton, S. Consumer generalization of nutrient content claims in advertising. *Journal of Marketing*, 62, 62-75, 1998.

Barone, M. J., Rose, R. L., Manning, K. C., & Miniard, P. W. (1996). Another look at the impact of reference information on consumer impressions of nutrition information. *Journal of Public Policy & Marketing*, 15 (1), 55-62.

Burke, S. J., Milberg, S. J., & Moe, W. W. (1997). Displaying common but previously neglected health claims on product labels: Understanding competitive advantages, deception, and education. Journal of Public Policy & Marketing, 16 (2), 242-255.

Burton, S., Andrews, J.C., & Netemeyer, R.G. (2000). Nutrition ad claims and disclosures: Interaction and mediation effects for consumer evaluations of the brand and the ad. Marketing Letters, 11(3), 1-13.

Derby, B.M. & Levy, A.S. (2001) Do food labels work? Gauging the effects of food labels pre-and post-NLEA. In P.N. Bloom & G.T. Gundlach (Eds.), Handbook of Marketing and Society. Sage, Thousand Oaks, CA, pp. 372-398.

Ford, G. T., Hastak, M., Mitra, A., & Ringold, D. J. (1996). Can consumers interpret nutrition information in the presence of a health claim? A laboratory investigation. Journal of Public Policy and Marketing, 15, 16-27.

Garretson, Judith A. and Scot Burton (2000), "Effects of Nutrition Facts Panel Values, Nutrition Claims, and Health Claims on Consumer Attitudes, Perception of Disease-Related Risks, and Trust," *Journal of Public Policy & Marketing*, 19 (Fall), 213-27.

Geiger, C. J. (1998). Health claims: History, current regulatory status, and consumer research. Journal of the American Dietetic Association, 98 (11), 1312-1322.

Hutt, P. B. (1986). Government regulation of health claims in food labeling and advertising. Food Drug Cosmetic Law Journal, 41, 3-73.

Jacoby, J., Handlin, A.H. & Simonson, A. (1994) Survey evidence in deceptive advertising cases under the Lanham Act: An historical review of comments from the bench. The Trademark Reporter, 84, 541-585.

Jacoby, J. & Morrin, M. (1998) Not manufactured or authorized by ...: Recent federal cases involving trademark disclaimers. Journal of Public Policy and Marketing, 17, 97-107.

Jacoby, J. & Szybillo, G.J. Why disclaimers fail. (1994) The Trademark Reporter, 84, 224-244.

Johar, G.V. (1995) Consumer involvement and deception from implied advertising claims. Journal of Marketing Research, 32, 267-279.

Keller, S. B., Landry, M., Olson, J., Velliquette, A. M., Burton, S., & Andrews, J.C. (1997). The effects of nutrition package claims, Nutrition Facts panels, and motivation to process nutrition information on consumer product evaluations. Journal of Public Policy & Marketing, 16 (2), 256-269.

The Keystone Center (1996). The Final Report of the Keystone National Policy Dialogue on Food, Nutrition, and Health. (March). Keystone, CO: Author.

Levy, A. S. (1996). Summary report on health claims focus groups. In The Final Report of the Keystone National Policy Dialogue on Food, Nutrition, and Health (March 1996), pp. 141-150. Keystone, CO: The Keystone Center.

Levy, A.S., Derby, B. M., & Roe, B. E. (1997). Consumer impacts of health claims: An experimental study. [On-line]. Available: <http://vm.cfsan.fda.gov/label.html>

Levy, A. S. & Fein, S. B. (1998). Consumers' ability to perform tasks using nutrition labels. Journal of Nutrition Education, 30 (4), 210-217.

Levy, A. S., Fein, S. B., & Schucker, R. E. (1996). Performance characteristics of seven nutrition label formats. Journal of Public Policy and Marketing, 15 (1), 1-15.

Levy, A. S., Fein, S. B., & Schucker, R. E. (1996). Performance characteristics of seven nutrition label formats. Journal of Public Policy and Marketing, 15 (1), 1-15.

Mason, M.J. & Scammon, D.L. (2000). Health claims and disclaimers: Extended boundaries and research opportunities in consumer interpretation. Journal of Public Policy and Marketing, 19(1), 144-150.

Mathios, A. D. & Ippolito, P. (1999). Health claims in food advertising and labeling: Disseminating nutrition information to consumers. In E. Frazao (Ed.), America's Eating Habits: Changes and Consequences (pp. 189-212). (Agriculture Information Bulletin No. 750). Washington, DC: U. S. Department of Agriculture.

Mazis, Micheal B. and Mary Anne Raymond (1997), "Consumer perceptions of health claims in advertisements and on food labels," *The Journal of Consumer Affairs*, 31 (1), 10-26.

Mitra, A., Hastak, M., Ford, G. T., & Ringold, D. J. (1999). Can the educationally disadvantaged interpret the FDA-mandated Nutrition Facts panel in the presence of an implied health claim? Journal of Public Policy and Marketing, 18 (1), 106-117.

Mojduszka, E. M. & Caswell, J. A. (2000). A test of nutritional quality signaling in food markets prior to implementation of mandatory labeling. American Journal of Agricultural Economics, 82, 289-309.

Moorman, C. (1998). Market-level effects of information: competitive responses and consumer dynamics. Journal of Marketing Research, 35 (1), 82-98.

Moorman, C. (1996). A quasi-experiment to assess the consumer and informational determinants of nutrition information processing activities: The case of the Nutrition Labeling and Education Act. Journal of Public Policy and Marketing, 15 (1), 28-44.

Murphy, D., Hoppock, T.H., and Rusk, M.K. Generic copy test of food health claims in advertising. Federal Trade Commission Staff Report, November, 1998.

Pearson and Shaw v. Shalala. United States Court of Appeals for the District of Columbia Circuit, January 15, 1999, No. 98-5043, Durk Pearson and Sandy Shaw, U.S. Department of Health and Human Services
[<http://www.cadc.uscourts.gov/common/opinions/1990001/98-5943a.txt>], 1999.

Roe, B. E., Levy, A. S., & Derby, B. M. (1999). The impact of health claims on consumer search and product evaluation outcomes: Results from FDA experimental data. Journal of Public Policy & Marketing, 18 (1), 89-105.

Russo, J.E., Metcalf, B.L. & Stephens, D. (1991) Identifying misleading advertising. Journal of Consumer Research, 8, 119-131.

Steinborn, S. B. & Todd, K. A. (1999). The end of paternalism: A new approach to food labeling. Food and Drug Law Journal, 54(3), 401-422.

Vladeck, D.C. (1999) Devaluing truth: Unverified health claims in the aftermath of Pearson v. Shalala. Food and Drug Law Journal, 54,535-553.

Vladeck, D.C. (2000). Truth and consequences: The perils of half-truths and unsubstantiated health claims for dietary supplements. Journal of Public Policy and Marketing, 19 (1), 132-138.

ATTACHMENTS

Attachment 1: Draft Questionnaire

QUESTIONNAIRE

INTRODUCTION: Thank you for agreeing to participate in this study of foods and food labels. Today you will be looking at some food labels for everyday food products. We are less concerned about how the labels look, than with what they say. None of these products are currently available for sale but they are similar to products you may have seen or purchased.

Please take a minute to look at this label.

A1. Does the label say or suggest anything about health benefits associated with this product?

1.....No (Skip to Q. A4)

2.....YES:

A2. What does the label say or suggest about health benefits associated with this product?

Pre-codes to be developed in pretests

Don't Know...98 Refused...99 Doesn't Say97

Now please turn to the next page. Please take a moment to look at the back label for this product.

A3. Overall, how important would this product be as part of a healthy diet? On a scale from 1 to 7, where 1 means "Very Important" and 7 means Not at all Important"

VERY	1	2	3	4	5	6	7	NOT AT ALL
IMPORTANT				NEITHER				IMPORTANT
				IMPORTANT				
				NOR				
				UNIMPORTANT				

Don't Know...98 Refused...99

A4. If you were going to eat this kind of food, would this product be a healthful choice?

VERY	1	2	3	4	5	6	7	NOT AT
HEALTHFUL				NEITHER				HEALTHFUL
				HEALTHFUL				
				NOR				
				UNHEALTHFUL				

A5. On a scale from 1 to 7, where 1 means "Very Likely" and 7 means "Not at all Likely," how likely is it that eating this product as a regular part of one's diet would ... ?

A5a. Reduce your risk of having a heart attack?

VERY	1	2	3	4	5	6	7	NOT AT
LIKELY				NEITHER				ALL
				LIKELY				LIKELY
				NOR				
				UNLIKELY				

Don't Know...98 Refused...99

A5b. Reduce your risk of having blood cholesterol?

VERY	1	2	3	4	5	6	7	NOT AT
LIKELY				NEITHER				ALL
				LIKELY				LIKELY
				NOR				
				UNLIKELY				

Don't Know...98 Refused...99

A5c. Reduce your risk of becoming overweight?

VERY	1	2	3	4	5	6	7	NOT AT
------	---	---	---	---	---	---	---	--------

LIKELY

NEITHER
LIKELY
NOR
UNLIKELY

ALL
LIKELY

(DO NOT READ) Don't Know...98 Refused...99

A6. Do you consider this product to be high, medium or low in ...?
(RANDOM START) .

NUTRIENT	HIGH	MEDIUM	LOW	DK	REF
a. Total Fat	3	2	1	8	9
b. Calories	3	2	1	8	9
c. Sodium	3	2	1	8	9
d. Trans Fat	3	2	1	8	9
e. Cholesterol	3	2	1	8	9
f. Saturated Fat	3	2	1	8	9
g. Calcium	3	2	1	8	9

A7. If you were going to buy this product in a store, how likely would you be to read ...?

- The claim that the product has 0 trans fat.
- The nutrition facts information about trans fat.
- The nutrition facts information about calories.
- The nutrition facts information about saturated fat.
- The information about how much trans fat you should eat

A8. Have you or has anyone *currently living in your household* ever ... (READ LIST OF CONDITIONS)

	YES	NO	DK	REF
a. Had heart disease?	1	2	8	9
b. Had diabetes?	1	2	8	9
c. Had high blood pressure?	1	2	8	9
d. Had a stroke?	1	2	8	9
e. Been treated for cancer?	1	2	8	9
f. Been treated for osteoporosis/brittle bones?	1	2	8	9
g. Been diagnosed as obese or overweight?	1	2	8	9

